

CORONET

Clear-Vue™ Recipient Vacuum Trepine (PK) Specification Sheet



Product Features:

- Patent protected soft adaptive skirt conforms to individual eye topography's
- Light weight body sits on limbus and forms a secure vacuum away from incision
- Ultra-thin and sharp blade with exclusive CORONET® Cathedral blade technology provides a straight walled cut and reduces endothelial cell loss
- Transparent body and open windows for 360 visualisation
- Ergonomic fingers grips and precision cross hair for improved control
- Marker pin for tracking blade progression
- Developed specifically for full Penetrating Keratoplasty surgery (PK)
- Supplied sterile, single use only, one per box, 5 year shelf life.
- Manufactured in the UK

*Blade progression 0.063mm downward per quarter turn and 0.252mm per full rotation.

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Recipient Vacuum Trepine Size Options

Trepine Size (mm)

Product Code

6.50	51-842-6.50
6.75	51-842-6.75
7.00	51-842-7.00
7.25	51-842-7.25
7.50	51-841-7.50
7.75	51-842-7.75
8.00	51-842-8.00
8.25	51-842-8.25
8.50	51-842-8.50
8.75	51-842-8.75
9.00	51-842-9.00
9.50	51-842-9.50

Material Specification

Product Component

Specification

Trepine Blade and cross hair	Stainless Steel (Blade Depth 1.15mm)
Trepine Body and finger grips	Polycarbonate
Skirt	Thermoplastic Elastomer
Black Capstan	ABS
Tubing	Medical Grade Silicone
Syringe	Luer-Lok (5ml capacity)
Blister Packaging	0.76mm PETG Blister/ TYVEK Lid (271mm x 82mm)
Outer Box/Carton	500 Micron Printed White Boxboard

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Intended Use

The CORONET® Recipient Vacuum Trephine is designed specifically for performing a full Penetrating Keratoplasty (PK) on the recipient eye, during corneal graft surgery.

Instructions for Use

The instructions for use and suggested surgical technique are supplied in the form of a multi-lingual leaflet with instructions given in diagram form where appropriate. The international symbols used on the packaging are explained in each language. A leaflet is supplied with each product

Sterilisation

Products are sterilised by Ethylene Oxide (EO) according to a validated cycle and the requirements of BS EN ISO 11135-1 (current).

Conformity to the European Directives

The CORONET® Recipient Vacuum Trephine is are classified as a surgically invasive device intended for transient use, (Rule 6, Annex IX 93/42/EEC Medical Devices Directive, as amended by 2007/47/EEC) and is therefore classified as a Class IIa device.